

CLAIMS :

1. Monolithic pharmaceutical composition comprising metformin hydrochloride as the active substance and hydrophobic polymer and or other hydrophobic material.
- 5 2. Composition of claim 1, wherein the sustained release dose for metformin hydrochloride is at least 1000 mg.
3. Composition of claim 1, wherein at least 74 % by weight of the composition is metformin hydrochloride.
- 10 4. The pharmaceutical formulation as defined in claim 1, wherein the hydrophobic polymer and or hydrophobic material is selected from the group consisting of Fatty acids, Fatty alcohols, Fatty acid esters, Hydrogenated oils, waxes and natural resins.
5. Composition of claim 4, wherein the hydrophobic polymer and or hydrophobic material comprises stearic acid, glyceryl monostearate,
15 glyceryl behenate, glyceryl pamtostearate, glyceryl monooleate, microcrystalline wax, stearyl alcohol, cetyl alcohol, cetostearyl alcohol, hydrogenated castor oil, tristearin, shellac, rosin, polyvinyl chloride powder, polyethylene powder, and the like.
6. Composition of claim 1, further comprising about 3 to 10% by weight
20 binder, up to 0.5 to 1.5% by weight glidant and up to 0.5 to 1.0% by weight of the lubricant.
7. Composition of claim 1, wherein pharmaceutical composition is tablet.

8. Process of producing a sustained release metformin hydrochloride composition of claim 1 which can be compresses comprising :

i) Granulating metformin hydrochloride and hydrophobic polymer and or other hydrophobic material by hot melt granulation or by extrusion.

ii) And drying the granulated product.

9. Process of claim 8, wherein the aqueous or organic solvent used in the granulation step contains a binder.

10. Process of claim 8, including the further step of compressing the dried granulated product into tablets.

11. Process of claim 10, including the further step of coating the tablet with a film envelope for taste neutralization.

12. Process of claim 10, wherein the compacted product further includes up to 1.5% by weight of lubricant, upto 1% by weight of glidant, and up to 4.5%by weight of binder.

13. The pharmaceutical composition according to claim 1 which releases metformin hydrochloride in a controlled and reproducible manner right from start and in the duration of minimum 8 hours.

14. The pharmaceutical composition of claim 1, used as oral antihyperglycemic agent in the management of noninsulin dependent diabetes mellitus (NIDDM).

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